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# **Terry Goddard Announces Landmark \$62 Million Pharmaceutical Settlement**

(Phoenix, Ariz. – October 7, 2008) Attorney General Terry Goddard today announced a record \$62 million dollar settlement with Eli Lilly and Company (Eli Lilly), relating to the company's alleged improper marketing of the antipsychotic drug Zyprexa®.

Today's settlement is the largest ever multi-state consumer protection-based pharmaceutical settlement. This settlement follows a \$58 million agreement with Merck in May 2008 regarding its product Vioxx. Arizona's share of today's settlement will be \$2,205,705.

In a complaint filed in Maricopa County Superior Court, Goddard, along with 32 other state Attorneys General, alleged that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa® for off-label uses - uses which are not approved by the U.S. Food and Drug Administration (FDA) - and for failing to adequately disclose the drug's potential side effects to health care providers. While a physician is allowed to prescribe drugs for off-label uses, law prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

"Patients must be able to feel confident that drug makers are advertising truthfully and providing complete and accurate information to their doctors," Goddard said. "Today's record-setting settlement sends a clear message to the pharmaceutical industry that deception or incomplete disclosure in any form will not be tolerated. Arizona families will be safer as a result of today's action."

Zyprexa® is the brand name for the prescription drug olanzapine. The drug was first marketed for use in adults with schizophrenia in 1996. Since then, the FDA has approved Zyprexa® for the treatment of acute mixed or manic episodes of bipolar I disorder and for maintenance treatment of bipolar disorder.

While these drugs may reduce the risk of these symptoms associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions. Zyprexa® has been associated with a high risk of weight gain, hyperglycemia and diabetes.

In late 2000, Eli Lilly began an aggressive marketing campaign called "Viva Zyprexa!" As part of that campaign, the company marketed Zyprexa® for a number of off-label uses. For example, it

marketed Zyprexa® for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions and in the elderly for the treatment and/or chemical restraint of patients suffering from dementia.

Following a one and a half year investigation by state Attorneys General, Eli Lilly agreed to change how it markets Zyprexa® and to cease promoting its off-label uses.

This settlement takes form of a consent judgment and does not constitute an admission of wrongdoing. The settlement mandates that Eli Lilly shall abide by the following terms for six years from the effective date of the judgment.

#### **Promotional Activities**

- Not make any false, misleading or deceptive claims regarding Zyprexa®.
- Not promote Zyprexa® using selected symptoms of the FDA-approved diagnoses unless certain disclosures are made regarding the approved diagnoses.

### **Dissemination of Medical Information**

- Require its medical staff, rather than its marketing staff, to have ultimate responsibility
  for developing and approving the medical content for all medical letters and medical
  references regarding Zyprexa®, including those that may describe off-label information.
  This information shall not be distributed unless certain criteria are met.
- Provide specific, accurate, objective and scientifically balanced responses to unsolicited requests for off-label information from a health care provider regarding Zyprexa®.
- Require its medical staff to be responsible for the identification, selection, approval and dissemination of article reprints containing more than an incidental reference to off-label information regarding Zyprexa®, and that such information not be referred to or used in a promotional manner.

## **Continuing Medical Education (CME) and Grants**

- Disclose information about grants, including continued medical education on its Web site, www.lillygrantoffice.com, for at least two years and maintain the information for five years.
- Not use grants to promote Zyprexa®, or condition CME funding on Eli Lilly's approval of speakers or program content.
- Contractually require continuing medical education providers to disclose Eli Lilly's financial support of their programs and any financial relationship with faculty and speakers.

## **Payments to Consultants and Speakers**

 Provide each signatory Attorney General a list of health care provider promotional speakers and consultants who were paid more than \$100 for promotional speaking and/or consulting by Eli Lilly.

## **Product Samples**

• Only provide product samples of Zyprexa® to a health care provider whose clinical practice is consistent with the product's current labeling.

### Clinical Research

Register clinical trials and submit results as required by federal law.

- Register all Eli-Lilly sponsored Phase II, III and IV clinical trials of Zyprexa® that began after July 1, 2005.
- Post all Eli-Lilly sponsored Phase II, III and IV clinical trials completed after July 1, 2004 on a publicly accessible Web site.

The consent judgment will be submitted to the Maricopa County Superior Court for court approval. A copy of the complaint is available on the Attorney General's Web site, <a href="https://www.azag.gov">www.azag.gov</a>.

Assistant Attorneys General Noreen R. Matts and Dena Rosen Epstein handled this matter. For more information, contact Anne Hilby (602) 542-8019.

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